

REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to highlight the differences between the claimed invention and the cited prior art. In this regard, claim 1 has been amended to provide an average particle size for the calcium-containing compound in the range of less than about 17 microns. Support for this amendment can be found in original claim 7 which as now been canceled.

In addition, claim 1 has been amended to provide that the centerfill portion has no gum base. Support for this limitation can be found throughout the specification and particularly in the first full paragraph on page 10 as well as page 11, lines 4-11 and in the Examples beginning on page 16 which clearly show the centerfill portion having no gum base therein (see Tables 1-3 on pages 16-18). It is therefore submitted that the amendments to claim 1 are fully supported in the application as filed and entry thereof is deemed proper and is respectfully requested.

It is also respectfully submitted that the amendments presented in response to the final Office Action do not require an additional search or extraordinary efforts on the Patent Examiner to ascertain patentability of the amended claims. Entry and consideration of the amendment is therefore deemed proper and is respectfully requested.

ARK:jsg111405/1901033.AMDFOA

Claims 1, 2, 4-9, 11, 13-16, 18, 19, 21-25, 27 and 29-33 stand rejected as unpatentable over Bell et al. (WO 00/06127). The rejection is hereby traversed and reconsideration is respectfully requested.

The rejection is based on comments made in prior Office Actions of May 18, 2004 and October 8, 2004. The Office Actions state that Bell et al. disclose a centerfill chewing gum composition including a shell portion and a centerfill portion. The centerfill portion includes a mixture of neutraceuticals and also present in the soft core may be a hydrocolloid. In addition, it is stated that the calcium in Bell et al. is inherently uniformly dispersed in the chewing gum due to the presence of the hydrocolloid.

The present invention is directed to a centerfill chewing gum in which gum base is absent from the core and a non-water soluble or sparingly water soluble calcium-containing compound is suspended therein while being uniformly dispersed without settling. This arrangement of the calcium-containing compound enables the centerfill chewing gum composition to be employed as a delivery vehicle to provide a minimum daily nutritional amount of calcium to a user by chewing a reasonable number of 3 to 5 pieces of the chewing gum composition per day.

In support of the patentability of claim 1 as amended, Applicants enclose herewith the Declaration of Jesse John Kiefer who is one of the principal inventors of the subject matter of the present application. The Declaration is being submitted in

unsigned form and the original executed Declaration will be forwarded to the Patent Examiner as soon as it is received.

Paragraphs 1-7 of the Declaration provide background for the invention and the motivation to provide a chewing gum composition capable of delivering an effective amount of a calcium-containing compound to the user. As indicated in paragraph 7, calcium fortification would naturally benefit from a calcium salt having a high calcium content. Calcium carbonate has a high calcium content (40%) making it an excellent choice of a calcium-containing compound for inclusion in a chewing gum composition. However, calcium carbonate, like many high calcium content salts is either water insoluble or only sparingly soluble in water. Thus, such calcium salts have an affinity for the water insoluble portion of the chewing gum base. This is highly undesirable because, as set forth in paragraph 8 of the Kiefer Declaration, when calcium compounds are in proximity to the gum base they become entrapped therein. This makes the calcium compound relatively unavailable for release into the oral cavity.

This has led to the development of a centerfill chewing gum composition which does not contain gum base so as to isolate the calcium-containing compound from materials which would prevent its release into the oral cavity. This is explained in detail in paragraphs 9 and 10 of the Declaration.

As indicated in paragraph 11 of the Declaration, merely placing calcium-containing compounds in a centerfill portion which is free from gum base still does

ARK:jsg111405/1901033.AMDFOA

not provide effective release because it is necessary to suspend and uniformly disperse the calcium compound within the centerfill portion.

Paragraph 12 of the Declaration explains that traditional suspending agents such as hydrocolloids and polyols alone do not eliminate settling. Thus, centerfill portions which contain calcium-containing compounds, even if provided with a suspending agent, are not effective in releasing a sufficient amount of calcium so that the chewing gum composition can serve as a nutritional supplement vehicle.

It is further required in the presently claimed invention that the particle size of the calcium-containing compound be reduced from what is typically employed through calcium supplements. In this regard, Applicants have amended their claims to limit the particle size of the calcium-containing compound to no more than about 17 microns. As indicated in paragraph 14 of the Declaration, when the average particle size for the calcium-containing compound is less than about 17 microns, the desirable suspension and uniform dispersion characteristics of the centerfill are achieved and a desirable chewing gum composition for the delivery of an effective amount of calcium is obtained.

Thus, the disclosure in Bell et al. of a conventional suspending agent for use in a centerfill portion does not teach or suggest the presently claimed invention. As previously indicated, the presence of a hydrocolloid alone in the centerfill portion does not provide the suspension and uniform dispersion characteristics which are required for the chewing gum composition of the present invention.

In addition, Applicants strenuously object to the conclusion in the prior Office Action that optimum viscosity and optimum particle size would be routine to one of ordinary skill in the art.

None of the references including Bell et al. describe the problems associated with prior art attempts at providing a chewing gum composition for the delivery of calcium. Bell has disclosed the use of a conventional suspending agent in the centerfill. But, as the Kiefer Declaration indicates, this is ineffective by itself to achieve the objects of the present invention. There is no motivation on the part of one of ordinary skill in the art, based on a review of Bell et al. to then employ the claimed particle size distribution for a calcium-containing compound which is nowhere disclosed in the reference. It was not routine for one of ordinary skill in the art to do what Applicants have done and there was no motivation to do so in the absence of an understanding of what is disclosed in the present application. It is therefore submitted that the rejection of the present claims based on Bell et al. alone should be withdrawn and such action is respectfully requested.

Claims 10, 12, 26 and 28 stand rejected as unpatentable over Bell et al. further in view of Cherukuri et al. This ground of rejection is deemed overcome in view of the amendment of the present claims to include the limitations set forth in previous claim 7 (i.e. an average particle size of less than about 17 microns). Furthermore, paragraphs 15 and 16 of the Kiefer Declaration address the issue of the disclosure of calcium carbonate as a filler in chewing gum compositions. First,

ARK:jsg111405/1901033.AMDFOA

Cherukuri et al. does not disclose a centerfill chewing gum composition in which the centerfill is free of gum base. The reference discloses a soft core portion which includes a particular type of gum base which is different than the conventional gum bases employed for chewing gum compositions. The Cherukuri et al. soft core portion therefore contains a gum base which tends to trap any non-water soluble or sparingly water soluble calcium-containing compound. Thus, it is improper to combine Cherukuri et al. with Bell et al. because Cherukuri et al. require the inclusion of the gum base in the centerfill portion. For this reason as well, the combination of Bell et al. and Cherukuri et al. is improper and the rejection based on these references should be withdrawn.

Claims 3 and 20 stand rejected over the combination of Bell et al. further in view of Friello et al. or Glass et al. The rejection is hereby traversed and reconsideration is respectfully requested. Claims 3 and 20 cover a Markush group of conventional suspending agents for inclusion in the centerfill portion of the chewing gum. However, neither Friello et al. or Glass et al. teach a centerfill chewing gum composition in which a calcium-containing compound which is non-water soluble or only sparingly water soluble is present in a very small particle size where the centerfill portion contains no chewing gum base. Accordingly, claims 3 and 20 are free of the prior art and withdrawal of the rejection of these claims is deemed proper and is respectfully requested.

Paragraphs 6-8 of the final Office Action set forth reasons why Applicants prior arguments were not deemed persuasive. With regard to paragraph 6,

ARK:jsg111405/1901033.AMDFOA

Applicants have shown that regardless of what calcium salts are employed by Bell et al., there is no teaching or suggestion of a system in which the particles of the calcium-containing compound are suspended and uniformly dispersed without settling to achieve the objects of the invention. In particular, there is no teaching or suggestion of the desired particle size range which is required for the chewing gum composition claimed herein.

Paragraph 7 of the Office Action indicates that Bell et al. teaches gum base in the core and/or the shell. Any calcium-containing compound of Bell et al. that is employed in proximity to the gum base would be lost as a potential calcium supplement. We have also shown that even if a calcium-containing compound was present in a portion of the gum which did not include a gum base, Bell et al. teaches no system for preventing settling of the calcium so that the chewing gum composition can be effective in releasing the calcium-containing compound into the oral cavity.

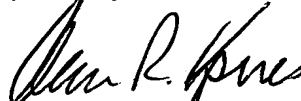
Finally, paragraph 8 objects to the claims because Applicants do not preclude gum base from the centerfill portion. Applicants have amended the claims to eliminate any possible gum base from the centerfill portion thereby obviating the objection to the claims set forth in the Office Action.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

ARK:jsg111405/1901033.AMDFOA

It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Allen R. Kipnes", written over the printed name and registration number.

Allen R. Kipnes, Esquire
Registration No. 28,433
Attorney for Applicant

Address All Correspondence to:

Allen R. Kipnes, Esquire
WATOV & KIPNES, P.C.
P.O. Box 247
Princeton Junction, NJ 08550
(609) 243-0330